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10/053,516	01/16/2002	Xianqiang Li	26757-710	1568

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryApplication No.
10/053,516Applicant(s)
LiExaminer
Arun ChakrabartiArt Unit
1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 15, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0903
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action

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DETAILED ACTION

Status of the Application

1. Applicant's amendment filed on August 15, 2003 has been entered. Claims 1, 3, 5, 6, 8, and 9 have been amended. New claims 10-17 have been added. Claims 1-17 are currently pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-17 are rejected under 35 U.S.C. 103(a) over Watt et al. (U.S. Patent 6,610,495 B1) (August 26, 2003) in view of O'Hare et al. (PCT International Publication Number WO 00/08182) (February 17, 2000).

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Watt et al. teaches a method for screening agents that affects protein degradation rates (Abstract), the method comprising:

i) expressing a fusion protein in each cell within a library of cells, the fusion protein comprising a reporter protein and a protein encoded by a sequence from a cDNA library derived from a sample of cells, the sequence from the cDNA library varying within the cell library (Example 2-3 and Figures 1-2);

ii) inhibiting further expression of the fusion protein to allow the expressed fusion protein to degrade in the cell (Claim 84, section V);

iii) selecting a population of cells from the library of cells based on the population of cells having different reporter signal intensities than other cells in the library, the difference being indicative of the population of cells expressing shorter lived fusion proteins than the fusion proteins expressed by other cells in the library (Claim 84);

iv) contacting the selected population of cells from step iii) with a plurality of agents which may affect protein degradation rates (Claim 84 and Examples 2-5);

v) for each agent, selecting cells in the selected population of cells from step iv) based on whether the cells have different reporter signal intensities than the cells in the selected population of cells from step iii) without being contacted with the agent, the difference being indicative of the selected cells expressing fusion proteins whose degradation is affected by the agent (Claim 84);
and

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d) characterizing the fusion proteins expressed by the selected cells for each agent (Claim 84 and Example 6).

Watt et al. teaches a method, wherein the method further comprises comparing which fusion proteins are expressed by the selected cells for each agent (Example 6).

Watt et al. inherently teaches a method for monitoring effects different growth conditions have on expression of proteins (Example 2), the method comprising:

- a) exposing samples of cells to different growth conditions (Example 2);
- b) forming cDNA libraries from the sample of cells after exposure to the different growth conditions (Figures 1-2 and Example 1);
- c) forming a library of cells for each cDNA library, the cells in the library expressing a fusion protein comprising a reporter protein and a protein encoded by a sequence from a cDNA library derived from a sample of cells, the sequence from the cDNA library varying within the cell library (Example 3);
- d) for each library of cells, identifying cells within the library that express fusion proteins that are degraded in vivo (Example 6), and
- e) characterizing fusion proteins expressed by the identified cells (Examples 4-6); and
- f) comparing which fusion proteins are characterized for each library of cells, differences in the characterized fusion proteins indicating differences in the proteins expressed by when the cells are exposed to the different agents (Examples 2-6).

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Watt et al. teaches a method, wherein exposing the samples of cells to different conditions comprises exposing the cells to different agents (Example 2).

Watt et al. teaches a method, wherein identifying cells within the library that express fusion proteins, comprises:

a) modifying a rate of protein expression or degradation by the cells (Column 27, lines 22-29 and Example 2), and

b) selecting a population of the cells based on whether the cells have different reporter signal intensities than other cells after the rate of protein expression or degradation has been modified, the difference being indicative of the selected population of cells expressing fusion proteins than the fusion proteins expressed by the other cells in the library (Claim 84 and Column 27, lines 30-34).

Watt et al. teaches a method for partitioning the library of cells into populations of cells based on an intensity of a reporter signal from the fusion protein such that cells partitioned into a given population have a reporter signal within a desired range of reporter signal intensity (Example 6).

Watt et al. teaches a method for screening for differences in proteins expressed by first and second cell samples (Example 4), the method comprising:

a) forming cDNA libraries from the sample of cells after exposure to the different growth conditions (Example 2);

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c) forming a library of cells for each cDNA library, the cells in the library expressing a fusion protein comprising a reporter protein and a protein encoded by a sequence from a cDNA library derived from a sample of cells, the sequence from the cDNA library varying within the cell library (Figures 1-2 and Examples 2-7);

d) for each library of cells, identifying cells within the library that express fusion proteins that are degraded in vivo (Examples 2-7), and

e) characterizing fusion proteins expressed by the identified cells (Examples 2-7); and

f) comparing which fusion proteins are characterized for each library of cells, differences in the characterized fusion proteins indicating differences in the proteins expressed by when the cells are exposed to the different agents (Examples 2-7).

Watt et al does not teach shorter lived fusion protein selected from green fluorescence protein.

O'Hare et al. teach shorter lived fusion protein selected from green fluorescence protein (Abstract and Figure 1 and 2 and Page 9, 5-32).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the shorter lived fusion protein selected from green fluorescence protein of O'Hare et al. into the method for detecting poteinacious inhibitors of protein-protein or DNA-protein interactions of Watt et al., since O'Hare et al. states, "The GFP example is especially advantageous because its fluorescence can be immediately and simply visualized and requires no extra processing steps (Page 4, lines 31-33)." An ordinary practitioner

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would have been motivated to combine and substitute the shorter lived fusion protein selected from green fluorescence protein of O'Hare et al. into the method for detecting proteinaceous inhibitors of protein-protein or DNA-protein interactions of Watt et al., in order to achieve the express advantages, as noted by O'Hare et al., of shorter-lived GFP which is especially advantageous because its fluorescence can be immediately and simply visualized and requires no extra processing steps.

Response to Amendment

4. In response to amendment, previous 102(b) rejection has been withdrawn. However, new 103(a) rejection has been included.

Response to Arguments

5. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau who can be reached at (703) 605-1237.

Arun K. Chakrabarti
ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

October 7, 2003

Gary Benzion
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